

Ex. 3

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January 19, 2018

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Re: Ms. Brenda Rozek

Dear Attorney Michael Coren:

I, Lloyd Saberski, Board Certified in internal medicine, anesthesiology, and pain management with an unrestricted license to practice medicine in the State of Connecticut, had an opportunity to review the medical records of Ms. Brenda Rozek and form opinions. The medical records reviewed were:

1. The medical records of Ritu Bhambhani, MD, August 13, 2012, August 30, 2012, and August 31, 2012, including what has been represented to me as the NECC prescription order form on which preservative free methylprednisolone acetate was obtained by Box Hill.
2. Union Hospital records September 8, 2012, through September 10, 2012.
3. Johns Hopkins Hospital September 8, 2012, through September 16, 2012.
4. Autopsy report on Ms. Brenda Rozek
5. Union Hospital records October 5, 2005, September 7 2012, through September 16, 2012.
6. Dr. Ritu Bhambhani Deposition February 10, 2016 and exhibits.
7. Dr. Ritu Bhambhani Deposition January 9, 2018 and exhibits.
8. Dr. Lloyd Saberski report, April 7, 2014
9. Common Issue expert report of Dr. Lloyd Saberski, September 11, 2016

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I also have reviewed the deposition testimony of Dr. Lucy Wilson of the Maryland Department of Health and Mental Hygiene who was involved in the Department's epidemiological investigation of the 2012 Fungal Infection Outbreak traced back to NECC, who concluded Ms. Rozek was a confirmed case and that her death was caused by the NECC MPA administered to her during her epidural steroid injection at Box Hill Surgical Center in 2012.

Nothing in the information I reviewed changes my opinions expressed in my earlier reports. Indeed, those opinions remain firm, particularly about the standard of care required of a physician using injectable steroids to know and understand the ingredients contained in and the source of medications they are prescribing for and injecting into their patients. As outlined below, Dr. Bhambhani did not comply with the standard of care in treating Ms. Rozek and her failure to do so was a significant cause of her death.

Ms. Brenda Rozek was a 51-year-old woman with a history of neck pain, hyperlipidemia, headache, and fibromyalgia who received a cervical epidural steroid injection on August 31, 2012. She subsequently developed profound headaches, slurred speech, right hemiparesis, left facial droop, and anisocoria.

A lumbar puncture performed on September 10, 2012, which had an opening pressure of 35 cm of water; glucose level of 1.998 millimoles/per liter (36 mg/per deciliter) with a serum glucose level at 105 mg/per deciliter; total protein level of 153 mg/per deciliter; white blood cell count of 850, 84% neutrophils, and 15% lymphocytes; and a negative gram stain and bacterial culture.

Treatment initially with acyclovir, cefepime, vancomycin, doxycycline, and methylprednisolone was initiated; however, she continued to deteriorate and develop dysphagia, leading to endotracheal intubation and transfer to the Johns Hopkins Hospital on September 11. Repeat MRI on September 13 showed new restricted diffusion in the left anterior thalamus, progression of brain stem infarction and edema, and interval development of ventriculomegaly, prompting placement of an externalized ventricular drain that did not result in clinical improvement; and by September 15, neurological examination progressed to absent pupillary, corneal, and gag reflexes; liposomal amphotericin B was added empirically. The patient expired on September 16, 2012, at 14:02.

Discussion: Therapeutic steroid injections have been utilized in medicine routinely for years, including spinal injections with corticosteroids. The standard of care requires that any injectable substance that a physician utilizes is safe, sterile, and prepared to accepted industry standards. Steroids utilized for injection are commercially available from various manufacturers and meet Federal Drug Administration requirements.

In the case of Ms. Brenda Rozek, the steroids used by Dr. Bhambhani were from NECC, a compounding pharmacy that manufactured methylprednisolone acetate without preservative in multidose vials. Through investigation, it has been found that compounded methylprednisolone at NECC were contaminated with various organisms,

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including fungi. Regrettably, the presence of contaminants, including fungi, when injected into susceptible patients like Brenda Rozek, caused life-threatening infection and, in the case of Brenda Rozek, death.

Dr. Bhambhani has testified that she utilized compounded MPA on the advice of a former colleague who suggested using preservative free steroids and, to her knowledge compound free steroids were not otherwise available. She also testified that when she opened her pain center, she effectively, did no investigation into the source of the medicine beyond asking an office manager from her prior center where they sourced their material. Her testimony also revealed some fundamental misunderstandings about compounding pharmacies, which, in my opinion, reflects a substandard knowledge base of prescribing.

Compounding pharmacies, by their nature, are to be used to compound medications tailored to the specific medical needs of a patient that cannot be met by FDA approved manufacturers. As they are supposedly making far less of any particular product, compounding pharmacies are not bound by the rigorous FDA manufacturing standards designed to assure the sterility, ingredient consistency and thus safety. It is, in part, why Massachusetts and Maryland regulations, among other states, dictate that compounded medications be obtained by patient specific prescriptions. And while FDA regulations do not eliminate all risks of contamination, they significantly reduce the risks and increase the safety of medicines that are manufactured. Dr. Bhambhani was aware of none of this information when she purchased and administered the NECC MPA to Ms. Rozek.

Although it should have raised a red flag about the nature of the pharmacy she was ordering from, Dr. Bhambhani claims she did not appreciate or understand that NECC's request that she use patient names from her past schedule on its prescription order form was inappropriate.

It is also important to observe that Dr. Bhambhani confirmed in deposition that her use of compounded MPA during Ms. Rozek's procedure in 2012 was a practice wide decision, in violation of the standard of care which required a patient specific need.

Because Dr. Bhambhani was unaware of the differences between manufactured and compounded deposit steroids, she never advised her patients, including Ms. Rozek, that the MPA she injected came from a compounding pharmacy rather than a manufacturer.

Dr. Bhambhani explained in testimony that she ordered from a compounding pharmacy as that was the only source of preservative free MPA – her objective was to only inject the steroid with nothing else into her patients. This decision making was flawed for two reasons. First, NECC's MPA contained preservatives, including polyethylene glycol (PEG) which was widely implicated as a cause of arachnoiditis when injected into the sub-arachnoid space. Second, there were FDA approved benzyl alcohol-free steroids available at the time. Again, Dr. Bhambhani's basis for using NECC's MPA reflects a sub-standard basis of knowledge and resulted in her use of a mass compounded product,

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thereby increasing the risks of precisely what occurred here.

Conclusions: The opinion expressed April 7, 2014 and in the September 11, 2016 Common Issue Expert Report remain unchanged after review of Dr. Ritu Bhambhani's January 9, 2018 Deposition and exhibits.

Based on my review of the above materials and my knowledge, training, and experience, it is my opinion, with reasonable medical probability or certainty, that Dr Bhambhani was negligent and violated acceptable standards of care by:

1. Failing to exercise reasonable and prudent care to ensure that the steroid preparations used for injections were sterile, free of contaminants, and compounded in accordance with all applicable industry standards.
2. Failing to exercise real and prudent care to ensure that the drugs purchased for therapeutic injections into Brenda Rozek were purchased from a drug manufacturer or compounder that reliably and consistently utilized proper quality control, safety, and sterility measures so as to minimize or eliminate the possibility that the drugs were not sterile or contaminated.
3. Failing to exercise reasonable care to avoid injecting Brenda Rozek with contaminated drug.
4. Failing to purchase and administer a steroid preparation with a preservative, such as Depo-Medrol for therapeutic injections, as opposed to injecting Brenda Rozek with preservative-free methylprednisolone.
5. Failing to properly inform Brenda Rozek that the steroid medication she was administered was not the Federal Drug Administration-approved drug Depo-Medrol but, rather, was a non-Federal Drug Administration-approved formula, namely, preservative-free prednisolone acetate.
6. Failing to warn Brenda Rozek of the risks and dangers associated with the injection of preservative-free steroid medication, including increased risk of infection.
7. Negligently using preservative-free multidose vials of steroidal preparations rather than single-dose vials.
8. Failing to comply with applicable statutes, regulations or guidelines governing the prescription and dispensing of compounded prescription medication for patients.

It is my opinion with a reasonable degree of medical certainty or probability that as a direct and proximate result of the violations of the standard of care by Dr. Ritu Bhambhani and the Box Hill Surgery Center as described above, claimant suffered a

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fungal infection with *Exserohilum rostratum*, which gave rise to a meningeal encephalitis and multiple vasculitic infarcts which ultimately led to Ms. Brenda Rozek's death on September 16, 2012.

Attorney, Coren, if you should have any further questions regarding my opinions, please do not hesitate to contact me.

I remain respectfully yours,

A handwritten signature in blue ink, appearing to read "Lloyd Saberski MD".

Lloyd Saberski, MD

Board certified Internal Medicine

Board certified Anesthesiology

Fellowship trained pain management specialist

Board certification / added qualification in Pain Management

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Department of Medicine

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Faculty University of Connecticut School of Medicine

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